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Gordon Prisk
UNIVERSITY OF CALIFORNIA SAN DIEGO

04/21/2016 Final Report

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AFOSR Final Report

FA9550-15-1-0116

Breath-Based Monitoring of Pilot Hypoxia – Proof of Concept

PI: G. Kim Prisk, PhD, DSc, Department of Medicine, University of California, San Diego.

Statement of Objectives (as submitted):

High performance fighter aircraft subsystems are routinely monitored to a very high degree, with over 1700 data streams recorded on the F22A Raptor, enabling a high degree of "forensic" analysis of any inflight "incident". Yet curiously the degree of monitoring of the pilot of the aircraft is minimal at best, despite the fact that the pilot is a critical element in any flight. This lack of monitoring of the pilot, an integral "system" in terms of aircraft flight, has hampered recent analyses of recent "hypoxia-like incidents" involving the F22A Raptor fleet.

This proposal addresses the <u>unmet need</u> of in-flight pilot monitoring for hypoxia in two ways:

- 1) by providing breath-by-breath monitoring of inhaled and exhaled O₂ and CO₂ together with airflow and mask pressure providing essential and direct information on pulmonary gas exchange (and thus hypoxia).
- 2) by providing monitoring of volatile organic compounds (VOCs) in exhaled breath that may be indicative of hypoxic stress.

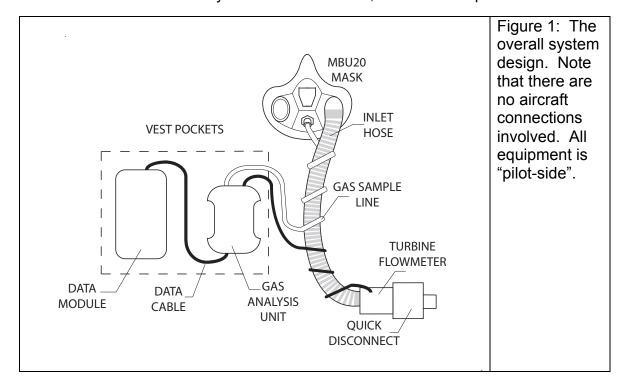
The outcome of this one-year proof-of-concept project will be a prototype system suitable for detailed evaluation and testing in ground-based simulations of inflight stresses such as with the reduced oxygen breathing device (ROBD), in altitude chambers, and under high-G conditions in centrifuge studies. Following such testing, if successful, flight-testing and evaluation would be indicated to provide an indication of operational potential and relevance.

Progress Towards Objectives

Development of a prototype system – The pilot breathing monitor

During this proof of concept development effort we have successfully developed a fully functioning prototype system suitable for further testing. This prototype system is based on a rapid response gas analysis unit (CareFusion Oxycon) which provides for continuous measurement of O_2 and CO_2 as well as flow, the latter using a turbine flowmeter. As indicated in Figure 1, the system is incorporated into the standard MBU-20 mask assembly in a non-intrusive manner and is designed so that the gas analysis unit is worn within a pocket of the pilot's vest. The flow meter is incorporated into the mask hose assembly and the gas

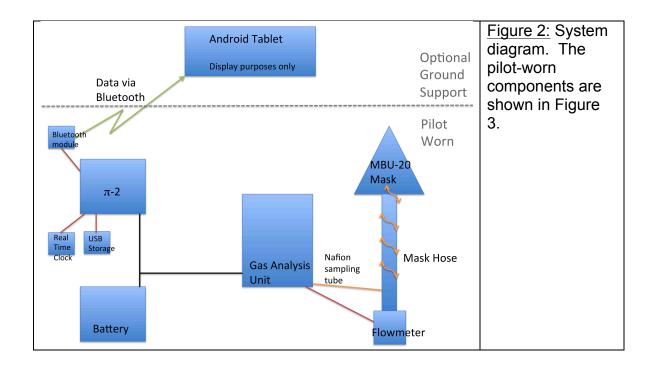
sampling tube is led down the hose to the analyzer. As such there are no connections between the system and the aircraft, all items are "pilot-side".



Data acquisition is via a dedicated microcontroller (see Figure 2, system diagram). This battery-powered module provides the following services:

- Power to the gas analysis unit
- Serial communication to/from gas analysis unit, which obtains all data.
- A real-time battery-backed clock module to provide date/time information
- Data storage to USB-connected Flash-RAM (storage depends on module size, 32Gb supported).
- Bluetooth transmission of data in real time
- Automated storage/transmission of all data (power-on initiates) data acquisition and storage permitting unattended operation. Data file names are unique and never overwritten.

The acquisition module is designed to be pilot-worn in the flight vest and has a single wired connection to the Analyzer unit. This wired connection can be configured prior to donning the vest, minimizing required pilot actions.



The complete prototype system is shown in the photograph in Figure 3.



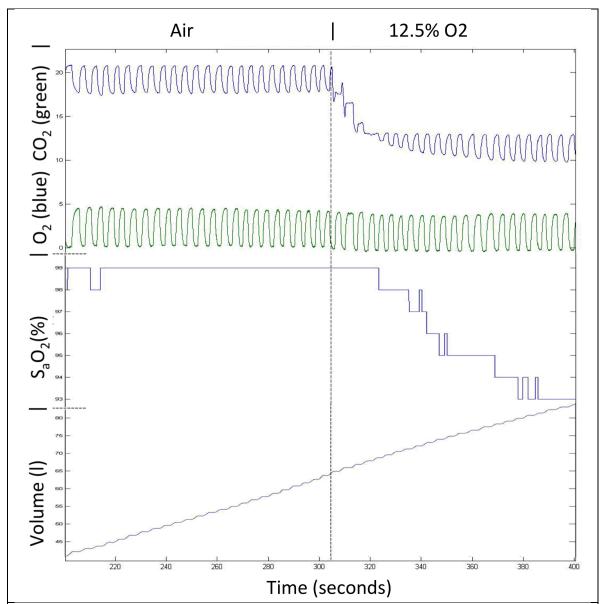
In addition to the pilot-worn part of the system described above, real time monitoring and visualization of the data are provided via an Android tablet (Figure 4). The tablet acquires the data transmitted using Bluetooth by the pilot worn system module and provides a real-time display both graphically and numerically and thus permits verification of data collection and quality. In circumstances where it is desirable to segment the data into separate files in the system module the Android software provides the facility to close the existing data file on the acquisition system and start a new file using a single button click.

It is important to recognize that while the Android display provides data visualization and some acquisition control, IT IS NOT REQUIRED for system operation. Simply powering the system module activates the gas analysis unit and begins data acquisition and storage automatically.



<u>Figure 4:</u> Android screen Shot during hypoxic breathing showing the accurate representation of both inspired and expired O_2 and CO_2 provided by the Pilot Breathing Monitor. Note that during steady state breathing of a hypoxic gas mixture of 12.5% O_2 , the arterial O_2 saturation is 88%. The Pilot Breathing Monitor provides a complete representation and capture of the gas exchange status of the pilot. Note also that the data shown on the Android device screen are stored in real time by the device and that this storage is automatic, continuous, and independent of the presence of absence of the Android device.

Figure 5 serves to provide an example of data collected during a normoxia-to-hypoxia transition (sea-level to 12,500 ft equivalent altitude). This was performed in multiple subjects, only one is shown. Importantly the data show the utility of the Pilot Breathing Monitor to rapidly detect the change in inspired gas concentration and the subsequent rapid change in expired concentrations. Note that these occur much more rapidly than the change in arterial oxygen saturation which lags the actual change in inspired gas by ~20 seconds and takes ~60 seconds to show a major effect. Such a rapid response is an important feature of the pilot breath monitor providing for rapid determination of the onset of a hypoxic challenge to the pilot.

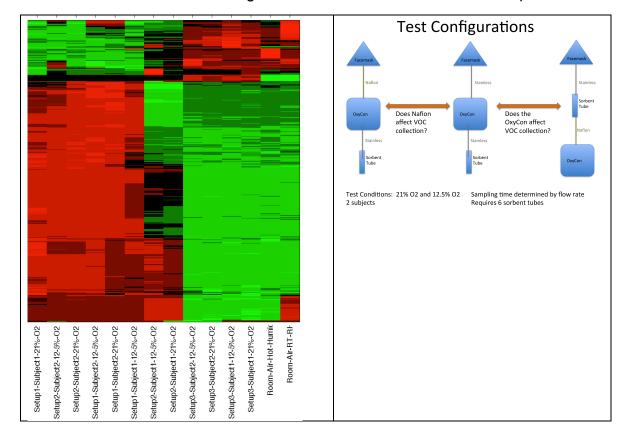


<u>Figure 5:</u> A normoxia to hypoxia transition. The inspired gas was switched at ~ 305 seconds and a rapid reduction in O_2 is seen in the gas concentrations. Note however that the response of the arterial oxygen saturation is much slower with no change for ~ 20 seconds and no evidence of a major fall in arterial oxygen saturation to below 95% for ~ 60 seconds. The ability to rapidly sense the hypoxia ia a major advantage of the Pilot Breathing Monitor.

Integration of volatile organic compound (VOC) monitoring with the pilot breathing monitor

In conjunction with Dr Claude Grigsby and others at the Air Force Research Laboratory (AFRL) we demonstrated the ability to simultaneously provide real and collection time monitoring of pilot hypoxia (as indicated above) and the collection of volatile organic compounds onto sorbent tubes. These tests included the evaluation of different configurations in which sorbent tubes were included in series with the Pilot Breathing Monitor using different configurations. Figure 6 shows results of one of these tests. In this instance 3 configurations were tested and the results indicate the important point that serial configurations present difficulties for both systems. Specifically, the Nafion tubing and the internal plumbing of the Pilot Breathing Monitor introduce undesirable VOC signatures into the sorbent tubes, as indicated by the lower red portions of the heatmap in Figure 6 and the addition peaks seen in the GC traces for systems 1 and 2. In contrast a direct stainless steel collection system provides a clean sample (the lower right green portion of the heat map, and the similarity between the GC trace for system 3 and the normal breath sample). However this configuration 3 serial sampling strategy (sorbent tube leading to Pilot Breathing Monitor) limits system response time (data not shown).

Based on these results a parallel sampling configuration is required and recent modifications to the mask configuration have demonstrated this to be practical.



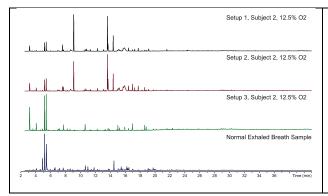


Figure 6: Heatmap, GC output and test configurations for the combined Pilot Breathing Monitor and Sorbent Tube test. The heatmap and GC output demonstrate that a parallel sampling configuration is required for simultaneous Pilot Breathing Monitor and sorbent tube collection studies. Such a configuration has been demonstrated to be feasible.

Future Work to Move this Project Forward

Following the successful demonstration of the proof of concept of the Pilot Breathing Monitor, and its ability to be incorporated with the collection of sorbent tubes for Volatile Organic Compounds (VOC), future work to develop the project involves the following.

- The equipment will be incorporated into a standard pilot vest and the small
 modification will be made to a standard mask and tested using a standard
 Reduced Oxygen Breathing Device ROBD. This equipment is routinely used for
 testing the effects of hypoxia on pilots, and will give us a good indication of how
 the new equipment can record data in these conditions. The time series sampler
 permitting serial collection of VOC signatures (in conjunction with AFRL).
- The equipment will be then tested on pilots during a simulated altitude ascent in a standard altitude chamber. This will allow us to record the physiological responses to hypoxia during ascent. In addition the test will validate the performance of the equipment at low barometric pressures.

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G. Kim Prisk

Program Manager

The AFOSR Program Manager currently assigned to the award

Dr. Patrick Bradshaw

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Abstract

This project addresses the unmet need of in-flight pilot monitoring for hypoxia by providing breath-by-breath monitoring of inhaled and exhaled O2 and CO2 (essential and direct information on pulmonary gas exchange and thus hypoxia), and providing monitoring of volatile organic compounds (VOCs) in exhaled breath that may be indicative of hypoxic stress. In this one-year proof-of-concept project we developed a prototype system suitable for detailed evaluation and testing in the future. The prototype system accurately measured both inspired and expired O2 and CO2 and inspired flow using a slight modification to the standard MBU-20 mask, that does not require pilot action. Gas concentrations and flow are recorded continuously on a module worn in the pilot vest, and there are no aircraft connections required. Operation is entirely automatic and data visualization is available via a Bluetooth connected tablet if desired (not required for routine operation). Tests of normoxia to hypoxia transitions from abrupt changes in inspired O2 show the utility of the system by detecting these changes well in advance of that measured by pulse oximetry. Testing with sorbent tubes to collected volatile organic compounds (VOC) in conjunction with AFRL shows that parallel operations are practical.

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